

### REMARKS

Claims 1-8 currently are pending.

Claim 7 is rejected under 35 USC § 101 because it is a use claim. To overcome the rejection, applicants amend claim 7 into a proper process claim.

Claims 4-6 were rejected under 35 USC § 112, second paragraph, because the examiner believes there is no antecedent basis for the limitation "compound of formula I" and "compound of formula II." To overcome the rejection, applicants replace "a compound of formula I" with a "compound of formula I as defined in claim 1" and "a compound of formula II" with a "compound of formula II as defined in claim 1" in claims 4-6 to overcome the rejection.

The examiner claims 1-3 and 8 were rejected as obvious over Buttle (*Exp. Opin. Invest. Drugs* (1996), 5(12): 1583-1587) and Wilding (*BMJ* Volume 315, 18 October 1997, pp. 997-1000). The examiner believes that to the skilled artisan, applicants' claimed subject matter would have been obvious because: 1) the references teach the treatment of obesity in general and as such, it is believed that the skilled artisan would have readily recognized that pathophysiological sequela of obesity would also be effectively treated; and 2) Wilding at page 1000, column 1, lines 8-11 teach "[t]here are many possible new therapeutic targets, and combinations of drugs with different modes of action may be required, as is currently the case with hypertension." Insofar as sibutramine and orlistat possess differing modes of action, it is believed that a combination of the two drugs is thus reasonably suggested.

Applicants respond by pointing out that there is no obviousness because of 1) the beneficial effect of the present invention being greater than that of sole administration of either a compound of formula I or compound II, 2) synergistic effects,

and 3) benefit obtained after administration of either a compound of formula I or the compound II has reached a plateau, 4) reduction in side effects, and that 5) lower dosages of each drug may be used when the combined is administered versus individual administration.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn.

**A check in the amount of \$920.00 is attached to cover the required three month extension fee.**

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read 'Daniel Kim', written in a cursive style.

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Amend claims 4-7 as follows:

4. (amended) A compound of formula I as defined in claim 1 including enantiomers and pharmaceutically acceptable salts thereof, in which  $R_1$  and  $R_2$  are independently H or methyl and the compound of formula II as defined in claim 1 for simultaneous, separate or sequential use for the treatment of co-morbid conditions associated with obesity.
5. (amended) A compound of formula I as defined in claim 1 including enantiomers and pharmaceutically acceptable salts thereof, in which  $R_1$  and  $R_2$  are independently H or methyl and the compound of formula II as defined in claim 1 as a combined preparation for simultaneous, separate or sequential use for the treatment of co-morbid conditions associated with obesity.
6. (amended) A product containing a compound of formula I as defined in claim 1 including enantiomers and pharmaceutically acceptable salts thereof, in which  $R_1$  and  $R_2$  are independently H or methyl and the compound of formula II as defined in claim 1 as combined preparation for simultaneous, separate, or sequential use for the treatment of co-morbid conditions associated with obesity,
7. (amended) [The use] A process of manufacturing a medicament for the treatment of co-morbid conditions associated with obesity in a patient who is also receiving treatment with orlistat comprising the step of incorporating into said medicament an effective amount of a compound of formula I including enantiomers and pharmaceutically

acceptable salts thereof, in which  $R_1$  and  $R_2$  are independently H or methyl [in the manufacture of a medicament for the treatment of co-morbid conditions associated with obesity in a patient who is also receiving treatment with orlistat].